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U.S. DISTRICT COURT
NORTHERN DIST. OF TX
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

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UNITED STATES OF AMERICA *ex rel.*)
ROBERT RICHARDSON,)

Plaintiff,)

v.)

INNOVASIS, INC.,)

DR. BRENT A. FELIX,)

AND)

GARTH L. FELIX,)

DEFENDANTS.)

Case No.

3-19CV-2440X

**COMPLAINT FILED UNDER SEAL
PURSUANT TO THE FALSE CLAIMS
ACT**

JURY TRIAL DEMANDED

QUI TAM COMPLAINT

Plaintiff Robert Richardson, as *qui tam* Relator (“Relator”), for himself and on behalf of the United States of America, alleges the following for his Complaint against Defendants Innovasis, Inc., a Utah corporation, and individuals Dr. Brent A. Felix and Garth L. Felix (collectively, “Defendants”).

Nature of the Case

1. This is an action by Relator to recover damages and civil penalties for Defendants’ violations of the False Claims Act (the “Act” or the “FCA”), 31 U.S.C. §§ 3729-3733, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). At the direction of Dr. Felix, an orthopedic surgeon, and his brother, Garth Felix (who are, upon information and belief, the principals, owners, and/or managing agents of Innovasis), Innovasis offered and paid illegal

remuneration totaling millions of dollars, from at least 2014 (if not earlier) until mid-2019, to a diverse group of approximately 20 orthopedic and neurological surgeons located around the country to induce them to purchase or cause the purchasing of Innovasis' spinal implants and related devices (the "Innovasis Products") for use during surgical procedures on their Medicare/Medicaid patients or other patients whose health care is paid for by federal government programs (such as Tricare¹ or the Federal Employees Health Benefits Program).

2. Defendants' conduct directly violated the Anti-Kickback Statute, which prohibits financial incentives to treating physicians to induce their purchase of medical devices, thereby resulting in false claims for payment to be submitted to and paid by federal health care programs, including Medicare, 42 U.S.C. §§ 1395 *et seq.*, Medicaid, 42 U.S.C. §§ 1396 *et seq.*, and other federal insurers, in violation of the FCA.

3. Innovasis utilized several types of arrangements as a cover for its illegal business dealings with the targeted surgeons, referring to them as "house accounts" and sometimes "legacy accounts." Dr. Felix and Garth Felix managed and serviced the house accounts almost exclusively, and information about them was kept secret from and inaccessible to most of the Innovasis staff. Those few individuals associated with Innovasis who have known of the house accounts include a cooperating witness here as well as: a director of marketing at Innovasis; a former Innovasis employee involved with Dr. Felix's cases and his brother-in-law; the principal for one of the limited liability companies created by Defendants to facilitate their illegal conduct (particularly regarding surgeons in the State of Ohio); a former Innovasis employee who was involved in setting up house account relationships in Ohio and Washington and resigned from Innovasis in 2018; and a current Innovasis employee who works on the finance and accounting

¹ Tricare is a federal medical benefit program for active-duty service members, retired military, and their dependents. *See* 10 U.S.C. §§ 1071-1110.

teams there, and thus closely with Garth Felix, where the employee gained familiarity with payments to house accounts.

4. Many of the house accounts were documented in writing. Some involved contracts for Innovasis to purchase intellectual property belonging to the surgeons or to “co-partner” with them to develop and bring to market items created from the surgeons’ intellectual property (i.e. “IP contracts”) as well as royalty agreements and consulting contracts.

5. Although Innovasis attempted to memorialize these arrangements in a manner to conform with the law, the way that Innovasis actually implemented the arrangements violated the Anti-Kickback Statute because the arrangements and the associated payments were tied to and intended to cause the surgeons’ choice of Innovasis Products over competing devices. Dr. Felix and Brent Felix directed members of the executive and sales teams at Innovasis to speak to and pressure surgeons subject to these contracts to increase the volume of Innovasis Products selected by the surgeons under the threat that their contracts with Innovasis would be cancelled.

6. The false appearance created by the contracts was particularly evident regarding the IP contracts. Innovasis entered into intellectual property acquisition contracts with physicians when there was no true product concept under development or Innovasis had no actual intention to support the development of the product. If a question arose from a surgeon about the product ostensibly being co-developed between the surgeon and Innovasis, employees in Innovasis’ product development division would have to admit that no structure was in place to develop the product or that Innovasis had failed to allocate any resources to develop the product. At times, a surgeon who truly believed in the potential of his concept would demonstrate frustration with the Innovasis development team because his idea for a new product would not be advancing—the Innovasis product development team felt that its hands were tied because

Innovasis, through Dr. Felix and Garth Felix, had refused to dedicate resources to the project. From Innovasis' perspective, the IP contracts were simply a sham or Innovasis to pay the surgeons to choose Innovasis Products over others available in the market, even if in some instances the contracts were ostensibly for the dual purpose of developing new product.

7. Regardless of their titles, the contracts deliberately masked collateral, side understandings between Innovasis and the surgeons about the expected high volume of purchases of Innovasis Products to be made by the surgeons in exchange for valuable financial compensation. Defendants expected, to the point of directly demanding either through themselves or through management and sales executives at Innovasis, that the physicians involved in "house accounts" (via their intellectual, royalty, and/or consulting agreements) purchase or cause the purchasing of high quantities of Innovasis Products in exchange for the compensation the physicians were receiving.

8. Garth Felix, in particular, created and maintained an "off the record" set of spreadsheets for Innovasis (kept off the public or "mainframe" computer drive at Innovasis) that closely tracked the surgeons' use of Innovasis Products as compared to the compensation they were receiving. The point of the spreadsheets was to determine if Innovasis was achieving the anticipated "return on investment" from the illegal remuneration arrangements. If a paid surgeon's purchase volume was too low, Innovasis pressured the surgeon to use more of its Products under threat of contract cancellation or simply terminated the contract associated with the physician.

9. Innovasis also does and has done business with a number of physician-owned product distributorships or "PODs." According to the Department of Health and Human Services Office of Inspector General (OIG), "[o]ne of the primary criticisms of PODs is that

ownership may affect physicians' clinical decision[-]making, such as influencing them to perform unnecessary surgeries or to choose a device in which they have a financial interest rather than another device that may be more appropriate for the patient." PODs "are inherently suspicious under the anti-kickback statute."²

10. Innovasis has engaged in unlawful promotion of its business interests and its corporate success has resulted primarily from activities that have violated federal law. The grouping of twenty or more orthopedic surgeons and neurologists having illegal contracts under "house accounts" with Innovasis (with their associated intellectual, royalty, and/or consulting agreements) accounted for approximately 60% of Innovasis' sales during the timeframe from 2014 to 2019 and generated \$60 million in sales revenue. Motivated by illegal financial incentives, the physicians selected Innovasis Products, largely indistinguishable from other implantable devices on the market, for procedures performed on their government-insured patients, which resulted in the submission of kickback-tainted false claims to Medicare, Medicaid, and other federal health care programs in violation of the FCA.

11. On behalf of himself and the United States, Relator seeks to recover all available statutory remedies for Defendants' knowing submission of false claims to the government, including treble damages, civil penalties, and Relator's reasonable expenses, legal fees, and court and other costs pursuant to 31 U.S.C. § 3730(d). As required by the FCA, this Complaint is filed under seal and will not be served on Defendants until further order of this Court.

The Parties

12. Relator is a citizen and resident of the State of Missouri. From February 2018 until September 2019, Relator was employed by Innovasis as its Area Business Director for the

² Majority Staff, Committee on Finance, U.S. Senate, 114th Cong. 2nd Sess., "Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern" (2016); HHS Office of Inspector General, "Special Fraud Alert: Physician-Owned Entities," Federal Register 78, no. 19271 (March 29, 2013).

Midwest region. While involved in marketing there, Relator obtained detailed knowledge of Innovasis' historical and current sales initiatives, including the existence of the "house accounts," Innovasis' relationship with at least one POD, and the quality of the Innovasis Products compared to other products on the market designed for the same purpose.

13. Relator personally discovered the existence of a questionable intellectual property agreement after receiving a voicemail from an angry surgeon around the 2019 Fourth of July holiday wherein the surgeon said he "hadn't received my check" under a contract with Innovasis on a product that was never developed or marketed. The contract was for \$250,000 over a two-year period on purported intellectual property that did not lead to anything of substance. No meaningful Innovasis resources were directed to developing the product, and the surgeon made no inquiry about the lack of progress to develop his alleged concept. With his contract coming to an end, the physician eventually stopped directing the purchase of Innovasis Products for his patients, and Innovasis was planning not to renew the contract because of the surgeon's lackluster performance: he did not purchase or cause the purchase of Innovasis Products in a sufficient quantity to justify his compensation.

14. In addition, Relator was one of several Innovasis employees who were told by Dr. Felix and Garth Felix that they needed to and were planning to "clean up" the "house accounts" and "surgeon deals" after becoming aware of, and speaking nervously about, the FCA lawsuit styled *United States ex rel. BNHT, LLC v. Life Spine, Inc., et al.*, pending in the United States District Court for the Southern District of New York.

15. Prior to his employment marketing Innovasis' products, Relator was involved in the marketing and sale of other orthopedic and neurologic medical devices, including for many years at Johnson & Johnson. While at Johnson & Johnson, Relator was a Senior Sales Manager

responsible for \$65 million in sales revenue and managed a team of over 4 managers, 40 product representatives, and distributors. Relator was employed by Johnson & Johnson for 20 years. Relator also has held sales-related positions with Boston Scientific, Abbott/St. Jude Medical, and Synaptive Medical. Relator accepted alternative employment after resigning from Innovasis in September 2019.

16. Relator is knowledgeable of the legal compliance requirements for physician marketing contact by the manufacturers and sellers of medical devices, including through Relator's employment at Johnson & Johnson. Relator always followed compliance requirements while at Innovasis and other employers. Relator holds a Masters of Business Administration from Rockhurst University in Kansas City, Missouri.

17. Despite his strong and lengthy experience selling implantable medical devices, Relator found the Innovasis offerings difficult to market because they were not pioneering but instead mimicked well-established product already on the market. Relator came to recognize the market pressure Defendants felt that may have motivated their wrongdoing, but Relator took no part in Defendants' improper scheme to defraud the government and resigned shortly after learning of the conduct. Relator has direct and independent knowledge of the facts underlying this Complaint, which have not been publicly disclosed, as that circumstance is defined under the FCA, 31 U.S.C. § 3730(e).

18. In addition to Relator's knowledge and experience, the allegations in this Complaint are supported by a cooperating witness, a former Innovasis executive, who has knowledge of the illegal compensation arrangements between Innovasis and surgeons, believed to have generated over \$60 million in revenue from the business relationships outlined in this Complaint between approximately 2014-2019.

Innovasis

19. Innovasis is a privately-held research, development, manufacturing, and marketing company specializing in spinal implant devices and related products primarily for the use of orthopedic surgeons and neurologists. Innovasis sells thoracolumbar, cervical, cranial, and biologic products, which Innovasis manufactures itself, explaining in its marketing materials that “[i]n the highly-regulated healthcare industry, Innovasis maintains all the quality controls of the manufacturing processes. This ensures the final product is something we are confident will serve our customers well, and protects us against future liabilities.”

20. Innovasis is a Utah corporation formed around July 2002 in good standing with that State as of the date of this Complaint and is authorized to conduct business and does conduct business throughout the United States. Innovasis markets itself throughout the United States and, upon information and belief, has sold its products in the majority of the states. Innovasis holds itself out as selling and distributing its products primarily through the use of independent distributors authorized to solicit sales of the medical equipment and products to the end users.

21. Innovasis was founded by Dr. Felix, and Dr. Felix is named in Innovasis’ Articles of Incorporation as the sole Director of the Innovasis Board of Directors and the holder of each officer title for the organization. Innovasis’ office is located at 614 E. 3900 S., Salt Lake City, Utah 84107-1902. Innovasis may be served with the Summons and Complaint via its registered agent in Utah, Lori Jackson, 9350 S. 150 E., Suite 820, Sandy, UT 84070.

Dr. Felix and his Brother, Garth Felix

22. Dr. Felix is a board-certified orthopedic surgeon. He is a citizen and resident of Utah and may be served with the Summons and Complaint at his residential address of 2911 E. Little Cottonwood Rd., Sandy, Utah 84092 or at his business addresses, which include Salt Lake

Orthopedic Clinic, St. Mark's Medical Office Building, 1160 E. 3900 S., Suite 5000, Salt Lake City, Utah 84124, or Alpine Orthopedic Specialists, 2310 N. 400 E., Suite A, North Logan, Utah, 84341 or Brigham City Clinic, 1030 Medical Drive, Brigham City, Utah 84302, or Innovasis, 614 E. 3900 S., Salt Lake City, Utah.

23. Upon information and belief, Dr. Felix implants Innovasis Products in his own Medicare and Medicaid patients and submits or causes to be submitted requests for payment or reimbursement for these devices to government programs, including Medicare and Medicaid, by the practice clinics and establishments where Dr. Felix treats patients. Upon information and belief, Dr. Felix has received compensation from Innovasis positively impacted by the volume of Innovasis Products that Dr. Felix chooses to implant in his own patients. At present, Dr. Felix has physician privileges at the Sale Lake Orthopedic Client, the Alpine Orthopedic Specialists Clinic, and the Brigham City Clinic.

24. Garth Felix is citizen and a resident of Utah and may be served with the Summons and Complaint at his residential address which is, upon information and belief, 1088 W. Park Meadows Dr., Mapleton, Utah 84664-4840. For many years, Garth Felix has been involved in all aspects of Innovasis' business operations and has had direct knowledge of and involvement in the improper physician remuneration arrangements by Innovasis described herein.

25. Dr. Felix and Garth Felix have ultimate control over all aspects of the operations of Innovasis. Upon information and belief, Dr. Felix and Garth Felix, directly or indirectly, are the majority owners of Innovasis. Dr. Felix and Garth Felix are not only at the top of the corporate hierarchy, they *are* the corporate hierarchy.

26. Upon information and belief, Dr. Felix and Garth Felix have shared interests in the following business entities understood to relate in one form or another to Innovasis' business

operations: Affirm Surgical Products, LLC, Balanced Holdings, LLC, Innovasis Properties, LLC, Mill Pond, LLC, Accuro, Inc, Summit R&D, LLC, and Innovasis Neurological, Inc. Upon information and belief, all are privately-organized limited liability companies or corporations formed under Utah law.

Jurisdiction and Venue

27. Pursuant to 28 U.S.C. §§ 1331 and 1345, this Court has original subject matter jurisdiction over this matter because it is a civil *qui tam* action under the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and alleges violations of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and thus involves questions of federal law. Relator is the original source of facts and information alleged in this Complaint, and is the original source disclosing the pattern of illegal activity by Defendants, and thus jurisdiction is not barred by 31 U.S.C. § 3730(e).

28. The Court has personal jurisdiction, and venue is proper, under 31 U.S.C. § 3732(a), which authorizes nationwide service of process in that an action under the Act “may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred.” 31 U.S.C. § 3732(a). At all times material to this action, Innovasis transacted business in the District, and submitted or caused the submission of false claims involving its products in the District.

29. Venue is proper in this District under 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims of this action occurred in this District, 28 U.S.C. § 1391(b)(2); or, pleading alternatively, (b) because Defendants are subject to specific personal jurisdiction in this State and District with respect to this action. Innovasis directed its

marketing to the State of Texas and this District via the Innovasis website (www.innovasis.com) and Defendants provided unlawful compensation to one or more physicians practicing in Dallas, Texas pursuant to a contractual arrangement.

Implantable Medical Devices and the Practice of Orthopedic Spinal Surgery

30. Physicians who perform orthopedic spinal surgery and neurosurgery function within one of the highest-paying medical specialties in the nation (neurosurgeons perform surgery on the brain and other parts of the nervous system, and orthopedists typically specialize in spinal surgery). With an aging population and the attendant existence of chronic conditions affecting the musculoskeletal system and the muscles, tendons, cartilage, joints and connective tissue that make it up, the number of patients seeking assistance from orthopedists and neurologists is growing.

31. Both neurosurgeons and orthopedic surgeons can perform spinal surgery, which almost always involves the use of an implantable device. “A medical device is defined as implantable if it is either partly or totally introduced, surgically or medically, into the human body and is intended to remain there after the procedure.”³ An implantable spine device is intended to correct a patient’s anatomy to address deformities, the effects of degenerative disease, or other problem conditions.

32. Innovasis markets its implantable devices to both neurosurgeons and orthopedic surgeons. Innovasis Products include implantable thoracolumbar, cervical, and cranial medical devices and related biologic supplies.

³ Johnson JA., FDA regulation of medical devices. Congressional research service, June 25, 2012 [Internet] Washington, DC: Federation of American Scientists; c2013. [cited 2013 Jul 13], <http://www.fas.org/sgp/crs/misc/R42130.pdf>, cited by Joung, Yeun-Ho in “Development of Implantable Medical Devices: From an Engineering Perspective,” Int. Neurourol J., 2013 Sep; 17(3): 98–106, U.S. National Library of Medicine, National Institutes of Health.

33. Innovasis Products are manufactured by Innovasis itself, and the company boasts of having the flexibility in its facilities to “rapidly” change its manufacturing process to respond to the market, even though Innovasis also describes regulatory authority over such devices as rigid: “[t]he flexible manner within the company allows Innovasis to move through the design, engineering, product development and production phases quickly and easily. When necessary, we can change individual aspects of a project rapidly and react to market changes almost instantaneously.”

34. Regulated by the federal Food and Drug Administration, Innovasis Products, upon information and belief, are considered like most other implantable devices to be intermediate risk (Class II) devices that can be cleared for market through a simple administrative review “if a company assures FDA that the device is ‘substantially equivalent’ to devices already available...this process does not require clinical testing to demonstrate safety or effectiveness of the device. As a result, many implantable devices arrive on the market without the benefit of studies that demonstrate their safety and effectiveness.”⁴

35. Medical devices, as defined by federal law, are used for both diagnostic and therapeutic objectives. Under federal law, reimbursable medical devices include any device intended for “human use” and certainly include Innovasis Products. *See* Federal Food, Drug, and Cosmetic Act, §201(h), 21 U.S.C. §321(h) (2010).

Paying for the Cost of Implantable Medical Devices

36. The cost of implantable devices is significant. “Some estimates have placed the price that hospitals must pay for implantable devices accounts at 30–80 percent of the payment

⁴ “Understanding the Market For Implantable Medical Devices,” Keith D. Lind, JD, MS, AARP Public Policy Institute, Aug. 2017 (the “Lind Article”), at pp. 1-2. *See also* James Robinson and Annemarie Bridy, “Confidentiality and Transparency for Medical Device Prices: Market Dynamics and Policy Alternatives” (University of California, Berkeley Center for Health Technology, October 2009), <http://bcht.berkeley.edu/docs/DevicePrices-Transparency-Report.pdf>.

they receive from insurers, such as Medicare, for related procedures.”⁵ The cost of implantables thus may exceed half of the reimbursement received from the health care insurer. Commentators predicted the U.S. implantable medical devices market would grow to be worth \$73.9 billion by the present time. Of that, “the orthopedic implant market will continue to remain the largest segment not only in terms of overall market value but growth rate as well.”⁶

37. Prices for medical devices are not transparent, including because manufacturers like Innovasis require their buyers to sign strict confidentiality agreements preventing disclosure of pricing information. This lack of transparency works to the benefit of the medical device manufacturers, namely because even if over-committed physicians making the choice of the medical device to use had the time and resources to compare prices for implantable devices, they would lack the data to reach any conclusion.

38. The lack of transparency at Innovasis extends beyond its product pricing to shield the identity of its founder and owner, Dr. Felix. Although he is a board-certified orthopedic surgeon who demands the use of Innovasis Products for his own patients, the Innovasis website contains no indication of Dr. Felix’s involvement with the company and no endorsement by him of the quality, usefulness, and value of Innovasis Products. Someone reviewing the information provided on the website would not learn that Dr. Felix has a personal financial interest in the sale of Innovasis Products.

39. Medicare, Medicaid, and other federal health care programs do not pay health care providers for implantables on a per-device basis. Rather, hospitals and other clinical

⁵ Lind Article, at p. 2. *See also* James Robinson and Annemarie Bridy, “Confidentiality and Transparency for Medical Device Prices: Market Dynamics and Policy Alternatives” (University of California, Berkeley Center for Health Technology, October 2009), <http://bcht.berkeley.edu/docs/DevicePrices-Transparency-Report.pdf>.

⁶ “U.S. Implantable Medical Devices Market Will Grow 8 Percent to \$73.9 Billion by 2018,” MedCity News, January 23, 2013, <http://medcitynews.com/2013/01/u-s-implantable-medical-devices-marketwill-grow-8-percent-to-73-9-billion-by-2018/>.

settings where orthopedic procedures are performed are reimbursed according to the total cost of the individual procedure, from start to finish. Hospitals and specialty clinics negotiate set “bundled package” fees for specific types of procedures. In this setting, determining the cost of the specific implantable device used in a given procedure is virtually impossible.

Choosing Which Implantable Medical Device to Purchase is Largely Predetermined

40. Implantable spinal devices can only be sold to health care providers. However, it is not the hospital or surgical center submitting the claims to government health insurance programs that decides which device to choose among those competing in the market. Spinal implant devices like the Innovasis Products are known as “physician preference” medical products, meaning that they are chosen by the individual surgeon performing the orthopedic or neurologic procedure or his/her staff. Innovasis’ exclusive market thus consists of individual physicians because even the hospitals and clinics where they have practicing privileges defer to and accept the physicians’ individual purchasing decision as to which implantable device to use.

41. “[D]evice manufacturers have created further hurdles to price competition through...brand loyalty, and financial ties, primarily to physicians who use the devices.”⁷ Indeed, “[h]ospitals...have limited bargaining power to negotiate lower prices. In addition to lack of price transparency, they also face ... [a] fragmented hospital industry, limited device data, and lack of control over buying decisions.” *Id.*

42. Because physicians provide the patient referrals that keep hospitals and surgical clinics operational, hospitals as the payors for implantables are understandably wary to interfere with or reject the choice physicians make as to an implantable device.

43. Physicians themselves have little incentive to identify the implantable providing the best value. “[P]hysicians rarely face liability for the cost of devices they implant under

⁷ Lind Article, p. 4 (citations omitted).

siloed payment mechanisms in fee-for-service systems.”⁸ Instead, physicians are vulnerable to financial manipulation by companies like Innovasis. “In 2015, medical device companies paid at least \$2.3 billion to health care providers in the United States...” *Id.*

Defendants’ Illegal Kickbacks to Physicians

44. Relator came to have personal awareness of the illegal marketing and business activities by Defendants in July 2019 after being contacted by a neurosurgeon practicing within Relator’s sales territory who claimed to be due a payment under his royalty contract with Innovasis. Relator was told by the Innovasis Vice President of sales that the neurosurgeon would probably stop using Innovasis product once his “deal” expires and “the only reason he is using Innovasis anyway is because we’re paying him.” Innovasis and the neurosurgeon had a royalty agreement relating to a medical product purportedly created by the neurosurgeon but that Innovasis did not use, develop, or sell.

45. When Relator inquired with Innovasis about the complaint from the neurosurgeon, Relator was told Innovasis would resolve it and, shortly thereafter, the payment being sought by the neurosurgeon was made by Innovasis through the directive of Dr. Felix and Garth Felix. This was even though there was no cause for any royalty payment by Innovasis because it had not used or sold any product created by the neurosurgeon.

46. Relator learned that Innovasis’ delay in making the contractual payment in the first instance was a pattern for its future relationship with the neurosurgeon. Because the surgeon had not caused the purchase of a sufficiently high enough level of Innovasis Products, the neurosurgeon had failed to meet the condition required for remaining a contracting party with Innovasis and his contract would be allowed to lapse.

⁸ Lind Article, p. 5 (citations omitted).

47. Relator investigated the matter to the extent information was available to him at Innovasis and came to believe that Innovasis had put in place a number of similar illegal payment and remuneration arrangements with surgeons such as the neurosurgeon. Some of these were “house accounts” managed and serviced almost exclusively by Dr. Felix and Garth Felix and had existed since at least 2014. Others were intellectual property arrangements, royalty agreements, and consulting agreements.

48. The “house accounts” involved the payments of intellectual property acquisition fees, royalty fees, and/or consulting fees to surgeons for their express or implied commitment to buy or cause their hospital or surgical clinic to buy Innovasis Products for use with their patients during surgery. Defendants expected to receive high percentages of product purchases relative to the compensation being provided to “house account” surgeons. Garth Felix kept detailed spreadsheets showing the “return on investment” to compare the amounts of sales to the financial payments received by the surgeons. Actively encouraged to make or cause to be made large number of purchases of Innovasis Products, the participating surgeons were criticized if they failed to sustain an acceptable level of purchases. For surgeons who did not order or cause the ordering of a sufficient volume of Innovasis products, Dr. Felix and Garth Felix would describe them as “under-performing” and a “bad investment” for Innovasis.

49. Upon information and belief, Innovasis has no equivalent analysis relating to any royalty for product created by a house surgeon or tracking the development of new product under an intellectual property contract. In fact, the Innovasis product development team would periodically receive inquiries from surgeons who truly were trying to develop a new product but would have to respond that the product was not being developed because Innovasis had refused to fund the necessary effort.

50. Upon information and belief, two members of the Innovasis Scientific Advisory Board, Ohio Surgeon 1 and Texas Surgeon 1, were “house accounts.”

51. Innovasis Scientific Advisory Board Member Texas Surgeon 1 (based in Dallas, Texas) had a “house account” with Innovasis prior to 2013 associated with an intellectual property contract under which he was, upon information and belief, awarded \$400,000 over the course of two years plus \$500/hour for consulting and three million performance shares. In 2014, Innovasis entered into a new agreement with Texas Surgeon 1, providing him \$300,000 at the inception of the contract plus \$840,000 paid quarterly over two years. In 2017, Texas Surgeon 1 and Innovasis entered into another contract, providing him \$100,000 at the inception of the contract plus \$800,000 paid quarterly over two years plus \$400,000/year in performance stock options at Innovasis for cervical products that were never developed. The true purpose of the payment was to incentivize Texas Surgeon 1 to purchase a large amount of Innovasis Products, which Texas Surgeon 1 did. Over time, Texas Surgeon 1 contributed \$10.4 million in sales revenue to Innovasis.

52. Innovasis had a similar arrangement with surgeons in Ohio (including Ohio Surgeon 1, who sits on the Innovasis Scientific Advisory Board) through a limited liability company called Accuro, Inc. (founded by an Innovasis employee in Nevada) and an Ohio-based LLC called Midwest R&D, LTD. Innovasis’ dealings in Ohio date as far back as 2006 and involved the development of a cervical system. Innovasis paid the surgeons over \$1,044,000 per year without ever taking a single meaningful step to develop the system. The true purpose of the payment was to incentivize the physicians to purchase a large amount of Innovasis Products, on an annual basis, which they did. The \$1.044 million payment resulted in sales of \$3 million of

Innovasis Products in 2018. The Ohio surgeons used over \$22 million in Innovasis Products from 2013-2018 and were paid kickbacks throughout that period.

53. Innovasis has, upon information and belief, nineteen “house accounts” that generated over \$60 million in sales revenue from 2013 to 2019.

54. According to Innovasis, its marketing ostensibly is performed by distributors, and Innovasis has described this as a course of business dealings between Innovasis, its distributors, and the ultimate end-user for the distributors to sell the products to on a consignment basis. Under the consignment sales arrangement described in Innovasis’ contracts with its distributors, called a Distributor Representative Agreement, Innovasis would ship products to the distributor, and the distributor would identify, market to, and sell the Innovasis products to potential customers. The customers would then place their orders either directly with Innovasis or through the distributor, and payment is made to Innovasis directly.

55. In truth, in addition to distributors, Innovasis has engaged in alternative marketing “efforts” in the form of illegal contractual relationships with “house accounts” and physician-owned distributorships. This marketing is done outside of an arrangement governed by any Distributor Representative Agreement.

56. As to those distributors whose networks included participating surgeons, Innovasis provided reduced commissions to the distributors because Innovasis already had its own independent arrangements with the surgeons. Orders generated or caused by the approximately 20 or so participating surgeons account for 60% of Innovasis’ gross revenue related to the sales of medical devices.

57. Further, upon information and belief, each “house account” involves on average 40-50% Medicare reimbursement because the typical surgical patient is over 60 years of age.

58. The United States, through the Centers for Medicare and Medicaid Services ("CMS"), administers the Supplementary Medical Financial Program for the Aged and Disabled, established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et. seq.

59. Medicare is a federally-funded health insurance program for those over age 65 and, in some measure, the disabled. Medicare beneficiaries may receive benefits under Part A, which covers up to ninety days of eligible inpatient hospital care for any single "spell of illness" at qualifying hospitals and will reimburse for an implantable device. Implantable devices are also reimbursable under Medicare Part B, insurance that helps pay for medical services and supplies provided by physicians and suppliers to Medicare beneficiaries not covered by Medicare Part A.

60. "House accounts" also involve Medicaid reimbursement. The Medicaid Program is part of the Social Security Act, which authorized federal grants to states for medical assistance to low-income, blind, or disabled persons, or to members of families with dependent children or qualified pregnant women or children. Medicaid is jointly financed by the federal and state governments.

Government Regulation of Medical Devices: the FCA and the Anti-Kickback Statute

61. The FCA provides, in relevant part, that anyone who "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim...is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000...plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). A "claim" is a "request or

demand . . . for money or property...presented to an officer, employee, or agent of the United States.” 31 U.S.C. § 3729(b)(2).

62. Under the Act, a person acts knowingly if he (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1)(A). While knowledge is a required element, specific intent to defraud the government is not. 31 U.S.C. § 3729(b)(1)(B).

63. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), prohibits any person or entity from offering, making, soliciting, or accepting remuneration, in cash or in kind, directly or indirectly, to induce or reward any person for purchasing, ordering, or recommending or arranging for the purchasing or ordering of federally-funded medical items, goods, or services: “whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.” 42 U.S.C. § 1320a-7b(b)(2).

64. While the Anti-Kickback Statute does not define “knowingly and willfully” as used in 42 U.S.C. § 1320a-7b(b)(2), in 2010, the Statute was amended to provide that “a person need not have actual knowledge of this section or specific intent to commit a violation of this

section.” 42 U.S.C. § 1320a-7b(h). The 2010 amendment “simply clarified that the government is not required to show a criminal defendant specifically knew the Anti-Kickback Act prohibited offering or paying consideration to induce referrals and intended to violate the law.” *United States v. Mathur*, No. 2:11-cr-00312-MMD-PAL, 2012 WL 4742833, at *15 (D. Nev. Sept. 13, 2012).

65. The Anti-Kickback Statute is a criminal statute, but a 2010 amendment provides that claims resulting from a violation of the Statute automatically constitute “false or fraudulent claims” civilly under the FCA. *See* 42 U.S.C. § 1320a-7b(g) (“In addition to the penalties provided for in this section or section 1320a-7a of this title [providing for civil monetary penalties], a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.”). In other words, a violation of the Anti-Kickback Statute is expressly treated as a false or fraudulent claim for purposes of the FCA. *See* 42 U.S.C.A. § 1320a-7b(g).

66. As codified in the Patient Protection and Affordable Care Act of 2010 (“PPACA”), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].”

67. According to the legislative history of the PPACA, this amendment to the Anti-Kickback Statute was intended to clarify “that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the [FCA], even when the claims are not submitted directly by the wrongdoers themselves.” 155 Cong. Rec. S10854. Compliance with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), is a condition of payment under Medicare and Medicaid.

68. The Anti-Kickback Statute exists to curb abuses like those engaged in by Innovasis, which has arrangements masquerading as lawful business dealings that, in reality, involve kick-back-tainted false claims that Innovasis submitted or caused to be submitted to federal government health care programs for the payment of Innovasis Products the purchase of which was induced by violations of the Anti-Kickback Statute.

69. After treating a Medicare patient and when submitting claims under Medicare or other federal programs, the submitter make the following certification that Innovasis' illegal conduct prevented from being true as to affected Innovasis Products:

In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) *this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law)*; 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license #, or SSN) of the primary individual rendering each service is reported in the designated section.

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf> (emphasis added). The Medicare Enrollment Application, CMS Form 855i, requires providers to certify “that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier’s compliance with all applicable conditions of participation in Medicare.”

70. The CMS 1500 form contains a provider certification for Medicaid claims and provides "... I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction. NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf>.

71. Innovasis' illegal conduct prevented the submitter from making true statements on the form as to the affected Innovasis Products.

CAUSE OF ACTION—VIOLATION OF 31 U.S.C. § 3729(a)

72. Relator incorporates by reference the foregoing allegations as if fully set forth herein.

73. In order to acquire income from payments through Medicare, Medicaid, and other federal health care program funds, including Tricare or the Federal Employees Health Benefits Program, Defendants knowingly and intentionally induced the purchase of Innovasis Products by medical health providers under directions from treating surgeons, and the providers then submitted, or caused to be submitted, claims and statements in support of claims to the federal government that were tainted by Defendants' conduct, which violated the Anti-Kickback Statute and thereby violated the FCA.

74. Defendants induced the purchase of Innovasis Products in violation of the Anti-Kickback Statute knowingly and with the specific intent to induce the government to reimburse the hospitals and surgical clinics whose physicians had selected Innovasis Products. Defendants'

involvement in paying the illegal remuneration to the physicians was material to the submission of the false and fraudulent claims and was a direct cause of the government's decision to make these payments. Defendants had full knowledge that physicians and the hospitals where the physicians performed surgeries were submitting claims to Medicare and other government health benefit programs that were false, fraudulent, and not payable because Defendants knowingly and willfully paid remuneration, financial incentives, to the physicians to induce their selection of Innovasis Product.

75. All of these misrepresentations and false certifications misled the government and induced it into paying substantial sums. These funds would not have been paid had the truth been known. As a result, the United States has sustained damages in an amount to be determined at trial.

76. While Relator does not have documentation for all of the practices described above, relevant information could be found in the following sources within Defendants' exclusive possession and control at Innovasis: accounts payable and receivable records, bank statements, internal financial statements, sales analysis records, return on investment studies on "house accounts," profit and loss statements, investment advisory statements, disclosures to investors/owners, contract summaries, contract-related records, information distributed by Innovasis sales representatives to distributors and prescribers, Innovasis records relating to compensation to sales distributors, and billing and insurance records.

77. Relator is ready and willing to cooperate in any investigation undertaken by the United States.

WHEREFORE, Relator prays for judgment against Defendants in the amount of three times the amount of claims paid by the United States of America to Defendant Innovasis, Inc.

pursuant to the false claims for payments to federal health care programs with which Innovasis was involved, for a civil penalty against Defendants in the maximum allowed statutory amount, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 for each violation of the False Claims Act, for the maximum amount otherwise allowed Relator under 31 U.S.C. § 3730(d) of the False Claims Act, for court costs, expenses, and attorneys' fees to Relator under 31 U.S.C. § 3730(d), and for such other and further relief as the Court deems just and proper.

NOTICE TO UNITED STATES

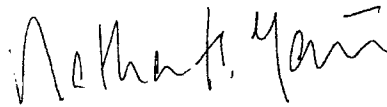
As required under the FCA, specifically 31 U.S.C. § 3730(b)(2), Relator has provided a copy of this Complaint and written disclosure of substantially all material evidence and information that Relator possesses to the Office of the United States Attorney for the Northern District of Texas simultaneous with the filing of this Complaint under seal.

Jury Trial Demand

In accordance with Fed. R. Civ. P. 38, Relator hereby demands a jury trial on all issues so triable.

Date: October 11, 2019

Respectfully Submitted,



/s/ Nathan F. Garrett

Nathan F. Garrett, TX 24063519

Kathleen A. Fisher, MO 57737

Pro Hac Vice Application Pending

Jennifer Donnelly, MO 47755

Pro Hac Vice Application Pending

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

This certifies that the foregoing was served on the Office of Erin Nealy Cox, Esq., United States Attorney for the Northern District of Texas, 1100 Commerce Street, Third Floor, Dallas, Texas 75242-1699, and the Office of William P. Barr, Esq., Attorney General of the United States, United States Department of Justice, 950 Pennsylvania Ave., N.W., Washington, D.C. 20530-0001, by placing same in the United States mail, first-class postage prepaid, on this 11th day of October, 2019.

Nathan F. Garrett

Attorneys for Plaintiff

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NORTHERN DISTRICT OF TEXA.

Innovasis, Inc., Dr. Brent A. Felix

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - (b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
 - (c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. [Click here for: Nature of Suit Code Descriptions.](#)
- V. **Origin.** Place an "X" in one of the seven boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
- Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
- PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If a related case exists, whether pending or closed, insert the docket numbers and the corresponding judge names for such cases. A case is related to this filing if the case: 1) involves some or all of the same parties and is based on the same or similar claim; 2) involves the same property, transaction, or event; 3) involves substantially similar issues of law and fact; and/or 4) involves the same estate in a bankruptcy appeal.

Date and Attorney Signature. Date and sign the civil cover sheet.



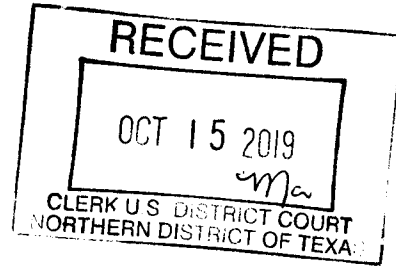
Graves Garrett LLC

Rebekah Badell
rbadell@gravesgarrett.com
Direct Dial: (816) 285-3047
Facsimile: (816) 256-5958

October 11, 2019

Via Federal Express

US District Court
Northern District of Texas
1100 Commerce Street
Room 1452
Dallas, TX 75242
Phone: (214) 753-2200



Re: Filing of *Qui Tam* Complaint Under Seal

Dear Clerk of the Court:

Enclosed please find the following documents to be filed under seal pursuant to the False Claims Act:

- an original complaint, and a copy of the same;
- a civil cover sheet;
- a check made payable to the US District Court;
- a certificate of interested persons; and
- a Relator's Confidential Evidentiary Disclosure in Support of the *Qui Tam* Complaint with accompany exhibits.

Please feel free to contact me if anything additional is needed.

Sincerely,

Rebekah Badell
Paralegal

Encl.

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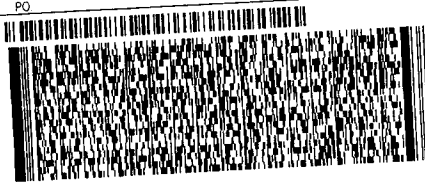
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